

### **Remarks**

This paper is being provided in response to the Office Action mailed December 28, 2007, for the above-referenced application. Claims 32-33, 39, 48, 49, 52-55, 58-62, 73, 74, and 77-81 have been cancelled. New claims 82, 83 and 84 have been added. Claims 1, 3, 12, 21, 25, and 29-31 have been amended. Applicant respectfully submits that the amendments to the claims do not add new subject matter.

### **Election/Restriction**

Claims 60-62, 73, 74, and 77-81 were withdrawn by the examiner. Appropriate status identifiers, indicating that these claims have been cancelled without prejudice, are included with this Response.

### **Claim Rejections under 35 U.S.C. § 112**

Examiner has rejected claims 1, 3, 6, 12, 21, 22, 25-33, 39, 48, 49, and 52-59 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner states that claim 1 is unclear as to whether the claim means to describe the composition prior to polymerization or after polymerization or both. Examiner further states that claim 1 introduces method steps and should be amended such that it does not recite both a product and method. Applicant has amended claim 1 to distinctly point out that which is claimed.

Examiner states that claim 3 likewise improperly recites both a product and method of using a product. Further, Examiner states that claim 3 recites a limitation without proper antecedent basis. Claim 3 has been amended to distinctly point out that which is claimed.

Examiner states that the “nature of protection” afforded by the elements of claim 21 and 29 are unclear. Claims 21 and 29 have been amended to distinctly point out that which is claimed.

Claims 32, 33, 39, 48, 49 and 52-59 have been cancelled. Claims 3, 6, 12, 21, 22 and 25-31 depend from amended claim 1. Applicant respectfully requests that the pending U.S.C. § 112 rejections be reconsidered and withdrawn.

### **Claim Rejections under 35 U.S.C. § 103**

Claims 1, 3, 6, 12, 21, 22, 25-33, 39, 48, 49, and 52-59 are rejected under 35 U.S.C. § 103 as being unpatentable over Evans et al. (U.S. Patent Publication No. 2003/0236573 A).

The Examiner states that Evans teaches a flowable implant for treating tissue defects, which may include a growth factor (*i.e.*, a bioactive protein), gelatin (which is both an insoluble material and a bioactive protein), and a photopolymerizable monomer (*e.g.*, FOCALSEAL) (*see* paragraph 139). The Examiner further states that Evans contemplates an embodiment in which the implant treats a tissue defect only at body temperature (paragraphs 127 and 139), and may further include polyethylene glycol as a filler (Table 4 at paragraph 7) and may include plasticizers other than polyethylene glycol, many of which are also cross-linked synthetic polymers (Tab 5 at paragraph 108). The Examiner continues that the composition of Evans inherently comprises light, *i.e.*, the light in the laboratory in which it is prepared.

The disclosure of Evans is directed towards a bone plug or implant that is suitable to be delivered and inserted into a defect in the bone of a living being for purposes of repairing/regenerating the same. *See, e.g.*, [0001], [0009], [0042] of Evans. The preferred embodiments throughout Evans are directed to implants comprising native fibrous collagen that delivers one or more biologically active agent to the bone defect. *See, e.g.*, [0081]-[0085], [0087]-[0089], [0091] of Evans. While Evans discloses a “flowable” material to be used as an implant that “could also photopolymerize like FocalSeal (Focal, Inc., Lexington, Mass.),” Evans does not disclose, teach or suggest (or enable one of ordinary skill in the art to reasonably expect success from) a substrate system comprising bioactive molecules, photo-polymerizable monomers, and an insoluble material that shields the bioactive molecules from a polymerizing process. Nor does Evans disclose a substrate system comprising an insoluble material that is a solid at below the body temperature of a living organism and a gel at the body temperature of a living organism.

The currently amended claims comprise photo-polymerizable monomers, bioactive molecules admixed with the monomers, and a material insoluble by the monomers and that shields the bioactive molecules from a polymerizing process, wherein the monomers cross-link to form a polymer that contains the bioactive molecules and insoluble material, and wherein the insoluble material is a solid at below the body temperature of a living organism and a gel at the body temperature of a living organism. *See, e.g.*, claim 1 of the present application. Unlike Evans, the presently amended claims address a concern that a polymerizing environment is deleterious to reactive molecules entrapped within the matrix, and therefore include an insoluble material that shields the bioactive molecules from the polymerizing environment. *Id.* Evans does not provide any structural limitations for overcoming the deleteriousness of the polymerizing environment. In fact, while Evans mentions that the material could “contain drugs or other agents” (*i.e.*, bioactive molecules [0139] of Evans), there is nothing in Evans or in the knowledge of one of ordinary skill in the art to suggest that the implant material as described by Evans can be polymerized without incurring a deleterious effect on the activity of the bioactive molecules.

Based on the above, Evans does not disclose, teach or suggest the amended claims of the present invention. Applicant therefore respectfully submits that Evans does not render the claims obvious, and respectfully requests that this rejection be reconsidered and withdrawn.

Based upon the above, Applicant respectfully requests that the Examiner reconsider and withdraw all outstanding rejections and objections. Favorable consideration and allowance are earnestly solicited. Should there be any questions after reviewing this paper, the Examiner is invited to contact the undersigned at 617-248-4054.

Respectfully submitted,

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